PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepravin Dry Cow 250 mg Intramammary suspension.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 3 g single dose syringe contains: cefalonium 250 mg in a long acting base.

3. PHARMACEUTICAL FORM

For intramammary infusion.

4. PACKAGE SIZE

20 syringes

5. TARGET SPECIES

see name of product

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Immediately after the last milking, clean teats and infuse the contents of one syringe into the teat canal. Avoid contamination of nozzle after removing cap.

Fig 1. After milking is complete, thoroughly clean and disinfect the end of the teat with the cleaning towel provided.
Fig 2(i). Option 1: For short nozzle intra-mammary administration hold the barrel of the syringe and the base of the cap in one hand and twist off the small upper part of

the cap above the indent mark (the base portion of the cap remains on the syringe). Take care not to contaminate the short exposed part of the nozzle.
Fig 2(ii). Option 2: For full nozzle intra-mammary administration remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.

Fig 3. Insert the nozzle fully into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.

Fig 4. Finally immerse the teats in a teat dip.

The syringe must only be used once. Part used syringes must be discarded.

8. WITHDRAWAL PERIOD

Do not use in the lactating cow.
Not intended for use within 54 days of calving.
Withhold milk for 96 hours after calving. Should a cow calve earlier than 54 days after treatment consult the package leaflet.

Cattle may be slaughtered for human consumption only after 21 days from last treatment.

For further information see enclosed package leaflet.

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT: Read instructions before use.

Penicillins/cephalosporins may occasionally cause severe allergic reactions - see package leaflet for user warning.

10. EXPIRY DATE

Expiry: end

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty syringes in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription. POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Store out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder in the UK:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4128

17. MANUFACTURER'S BATCH NUMBER

Batch No: CSSA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepravin Dry Cow 250 mg Intramammary suspension.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 3 g syringe contains: cefalonium 250 mg.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 g syringe

4. ROUTE(S) OF ADMINISTRATION

Intramammary suspension.

5. WITHDRAWAL PERIOD

Milk withdrawal period: 54 days after last treatment plus 96 hours after calving.
Meat withdrawal period: 21 days.

Read package leaflet, including operator warnings, before use.
Keep the container in the outer carton.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry: end

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

To be supplied only on veterinary prescription. POM-V
MA number Vm 06376/4128

PACKAGE LEAFLET FOR:

Cepravin Dry Cow 250 mg Intramammary suspension.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation holder:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepravin Dry Cow 250 mg Intramammary suspension.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each single dose 3 g syringe contains 250 mg cephalonium in a long-acting base.

Presentation
Cepravin Dry Cow is a long-acting intramammary cerate containing cefalonium, a semisynthetic cefalosporin antibiotic. It is formulated to give persistent antibiotic levels in the dry udder. Effective levels of cefalonium are usually present in most quarters for up to 10 weeks after intramammary infusion at drying-off.

4. INDICATION(S)

Uses
Cepravin Dry Cow is recommended for routine dry cow therapy, to treat existing subclinical infections and to prevent new infections which occur during the dry period.
Cefalonium is a broad spectrum cephalosporin antibiotic which has bactericidal activity against the majority of organisms associated with bovine mastitis. This antibacterial activity is not impaired in the presence of milk.

Cefalonium is active against *Staphylococcus aureus*, including penicillin-resistant strains, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Actinomyces pyogenes* and *Corynebacterium ulcerans*. Strains of *Strep. uberis* and *E. coli* isolated from postcalving mastitis cases were sensitive to cephalonium.

Cattle treated with Cepravin DC generally have a lower incidence of S*treptococcus uberis* infection during the dry period and the immediate post-calving period, with accompanying lower somatic cell counts.

The antibiotic was also active against environmental organisms r*ecovered from the bovine udder, including Proteus spp., Klebsiella spp., Citrobacter* spp., and Enterobacter strains.
Effective levels of cefalonium are maintained in most quarters for up to 10 weeks after infusion of Cepravin Dry Cow.

5. CONTRAINDICATIONS

Contra-indications, warnings, etc

Cepravin Dry Cow must not be used in the lactating cow. Not intended for use within 54 days of calving.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cepravin Dry Cow

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and administration

For intramammary infusion.
The contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Before infusion, the teat should be thoroughly cleaned and disinfected. Avoid contamination of the nozzle after removing the cap. After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

9. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Fig 1. After milking is complete, thoroughly clean and dis infect the end of the teat with the cleaning towel provided.

Fig 2(i). Option 1: For short nozzle intra-mammary administration hold the barrel of the syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the syringe). Take care not to contaminate the short exposed part of the nozzle.

Fig 2(ii). Option 2: For full nozzle intra-mammary administration remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.

Fig 3. Insert the nozzle into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.

Fig 4. Finally immerse the teats in a teat dip.

10. WITHDRAWAL PERIOD(S)

Protection of consumers.

Milk for human consumption may only be taken from 96 hours after calving.
If calving occurs before 54 days after treatment, milk for human consumption may only be taken after 54 days plus 96 hours after treatment, ensuring that the milk from at least 7 complete milkings is discarded.

The absence of antibiotic should be confirmed by testing before the milk is used for human consumption. This is advisable because of variation in the milking cow's ability to excrete antibiotic from dry cow products.

In cows suffering from hypocalcaemia, it may be necessary to discard milk for a longer period.

Animals for human consumption should not be slaughtered until 21 days after last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.
Store out of reach and sight of children.

12. SPECIAL WARNING(S)

For Animal Treatment Only

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from milk samples from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalonium and may decrease the effectiveness of treatment with other beta lactams. Dry cow therapy protocols should take local and national policies on antimicrobial use into consideration, and undergo regular veterinary review.

The feeding to calves of milk containing residues of cefalonium that could select for antimicrobial-resistant bacteria (e.g. production of beta-lactamases) should be avoided up to the end of the milk withdrawal period, except during the colostral phase.

The efficacy of the product has only been established against pathogens sensitive to the active substance. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, particularly *Pseudomonas aeruginosa*, can occur after drying off. Good hygiene practices should be thoroughly respected in order to reduce this risk.

Operator warnings

Penicillins and cefalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact.

Hypersensitivity to penicillin may lead to cross reactions to cefalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the Doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
4. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty syringes in accordance with guidance from your local waste regulation authority.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Package quantities

Boxes of 20 syringes and cleaning towels, 'Herd Pack' of 200 syringes (10 boxes of 20 syringes and cleaning towels).

Not all pack sizes may be marketed.

Legal category

To be supplied only on veterinary prescription.

POM-V

Further information.

If the product is used in heifers during their first pregnancy the same precautions should be observed as in cows, ie. infusions should be given no less than 54 days before calving and milk discarded for the statutory four days after calving.

Summer mastitis

It is unlikely that antibiotic treatment alone will control Summer Mastitis and therefore other measures should be implemented as part of routine management.

These measures include:

a) Practising some form of fly control on the farm.

b) Avoiding pasturing cattle on wet or wooded fields which are known to be associated with Summer Mastitis.

c) Post-infusion teat dipping of cows and heifers receiving prophylactic intramammary infusions for the disease.

d) Prompt attention to teat injuries or sores as these rapidly attract flies.

e) Farms with an intractable problem should consider changing the calving pattern to avoid having animals at risk during the summer months.

Marketing Authorisation number: Vm 06376/4128

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

Gavin Hall

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